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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/484,629	01/18/00	ROBINSON I	3265/85705

EXAMINER

027495
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/484,629	Applicant(s) ROBINSON ET AL.	
	Examiner Joseph Woitach	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *1-7,17-27 and 29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-16 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This application is an original application filed January 18, 2000, which claims benefit to foreign applications: PCT/GB99/02658, filed December 8, 1998; 9817566.4, filed August 12 1998; and 9910522.3, filed May 6, 1999, all filed in the United Kingdom.

Applicants amendment filed June 8, 2001, paper number 21 has been received and entered. The specification has been amended. Claims 6, 7 and 10 have been amended.

Applicant's election with traverse of Group II, claims 8-16 and 28 in Paper No. 15 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-7, 17-27 and 29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 15.

Claims 1-29 are pending, claims 1-7, 17-27 and 29 are withdrawn from further consideration as drawn to a non-elected invention, and claims 8-16 and 28 are currently under examination.

Sequence compliance

Applicants amendment filed April 5, 2001, paper numbers 14 and 15 have been received and entered. The application is now in sequence compliance.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

In addition, receipt is acknowledged of papers filed under 35 U.S.C. 119 (a)-(d) based on two applications filed in Great Britain on August 12, 1998 and May 6, 1999. Applicant has not complied with the requirements of 37 CFR 1.63(c), since the oath or declaration does not acknowledge the filing of any foreign application. A new oath or declaration is required in the body of which the present application should be identified by application number and filing date. Further, if application PCT/GB99/02658, filed August 12, 1998, qualifies for benefit of priority under 35 USC 120, Applicant may wish to indicate in the substitute declaration this claim to priority, as well as provide the necessary supporting papers. The claim for priority is confusing in view of the transmittal letter which appears to be correct, and the declaration which has been filed which only claims benefit to PCT/GB/99/02658 under 35 USC 119.

It is recommended that a new oath or declaration be filed clearly claiming benefit to the PCT and the foreign applications under the correct statutes so that priority can be granted.

Priority

Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon application PCT/GB/99/02658 filed in Great Britain on August 12, 1998 (in declaration) and application 9817566.4 filed in Great Britain on August 12, 1998. A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said application, since the United States application was filed more than twelve months thereafter. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Great Britain on May 6, 1999. The claim for priority is confusing in view of the transmittal letter which appears to be correct, and the declaration which has been filed which only claims benefit to PCT/GB/99/02658 under 35 USC **119**. As noted above, it is recommended that a new oath or declaration be filed clearly claiming benefit to the PCT and the foreign applications under the correct statutes so that priority can be granted. In addition, it is noted that applicant has not filed a certified copies of the application as required by 35 U.S.C. 119(b).

Specification

The disclosure is objected to because of the following informalities: The specification contains several references to a URL (for example: page 11, last paragraph; page 12; line 5--review of the entire specification is recommended). The attempt to incorporate subject matter into the patent application by reference to a hyperlink an/or other forms of browser-executable

code is considered to be an improper incorporation by reference (See MPEP 608.01(p)). Appropriate correction is required.

Claim Objections

Claims 8-16 are objected to because of the following informalities: Claims 8-16 are dependent on non-elected claims. Elected claims should be amended to encompass all the limitations of the independent claim and any intervening claims for claims drawn to the non-elected invention. Appropriate correction is required.

Claims 8-16 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must refer to a single dependent claim in the alternative. See MPEP § 608.01(n). For the sake of compact prosecution the claims will be read as if the dependency of the claim is written in the alternative, and as drawn to the specific limitation set forth in the non-elected claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-16 and 28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey

to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In view of the teachings of the instant specification, the polynucleotide sequences which encode the polypeptide sequences set forth in SEQ ID NOs: 2, 4, 6 and 16 and the polynucleotide sequences set forth in SEQ ID NOs: 1, 3 and 16, meet written description the mutants, however, substantially homologous sequences, and equivalents thereof recited and encompassed by the claims do meet the written description provision of 35 U.S.C. §112, first paragraph

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" Vas-Cath Inc. v. Mahurkar, 19USPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."Vas-Cath Inc. v. Mahurkar, 19USPQ2d at 1116.

The specification fails to describe any 5'OT EST polynucleotide sequence beside those defined by SEQ ID NOs in the present specification. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art as of Applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed invention as a whole) such that a person skilled in the

art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). In the instant case, the claimed embodiments of the nucleic acid encoding a sequence substantially homologous to the polypeptide sequences set forth in SEQ ID NOs: 2, 4, 6, or equivalents and mutants, thereof specifically recited in non-elected claims 1-7 and polynucleotide sequences which hybridize to 20 base pair oligonucleotide sequences, or substantially homologous sequences to the polynucleotide sequences set forth in SEQ ID NOs: 1, 3 and 31 encompassed by claims 8-16 and 28, lack a written description. The specification provides one example of truncated form of the 5'OT EST with a unique carboxyl terminal amino acid sequence which confers an activity in transgenic rats, however the specification fails to describe any species within the genus of a polynucleotides encompassed in the claims with particularity to indicate that Applicants had possession of the claimed invention. The specification does not describe what the endogenous form of 5'OT EST does, nor what types of alterations to the polynucleotide sequence the artisan should make to generate the broad range of sequences encompassed by the claim. For example, while it is clear that the single mutant form of 5'OT EST has a unique activity in the transgenic rat, there is no teaching to indicate if this is due to remaining truncated 5'OT EST, the lack of the 5'OT EST carboxyl terminal or the new sequence introduced by the deletion/frame shift in the transgene construct. Without guidance to the endogenous function of the 5'OT EST or guidance or the basis of the single 5' TO EST mutant activity, the artisan cannot define the metes and bounds of what is encompassed by substantially homologous and equivalents of the 5'OT EST. Further, even if the sequence would

hybridize to a 20 base pair oligonucleotide, lacking a definable function or some other defining feature, the artisan is left to guess if the polynucleotide would be encompassed by the claim sharing only a small percentage of homology. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art **as of Applicants effective filing date**. The skilled artisan cannot envision what changes can be made to the nucleic acid sequences and not affect the biological activity, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, though a polynucleotide sequences which encode the polypeptide sequences set forth in SEQ ID NOs: 2, 4, 6 and 16 and the polynucleotide sequences set forth in SEQ ID NOs: 1, 3 and 16, meet written description the mutants, substantially homologous sequences, and equivalents thereof recited and encompassed by the claims do meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear

that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-16 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8-16 are dependent on non-elected claims which are multiple dependent claims, and because of the multiplicity of all the possible combinations, the limitations of these claims are not clear. Further, claims 9-16 are unclear in the recitation of 'claims 1-7 claim **X**' (where **X** varies form claim to claim) because the second 'claim **X**' is not recited in the alternative relative to claims 1-7, and it is not clear how the choice of dependent claims are related. Amending the claims to more clearly indicate the dependency or to recite the specific embodiments recited in the non-elected claims is necessary.

Claim 9 is indefinite because the metes and bounds encompassed by 'substantially homologous' are not clearly defined. Without specific % homologies or hybridization conditions to define the sequences, the artisan would not know how to define what amount of homology which would be considered substantial.

Claims 9 and 10 are unclear because it recites 20 contiguous base pairs of SEQ ID NOs, however some of the SEQ ID NOs, numbers 5, 7 and 16, are polypeptide sequences.

Claim 10 is vague and unclear in the recitation of 'sequence substantially homologous thereto' because the metes and bounds which are encompassed by substantially homologous are not clearly or specifically defined in the specification. The claims could encompass polynucleotide sequences which would not even encode the same or functionally equivalent 5'OT EST polypeptide, and because the specification discusses mutant forms of 5'OT EST, the artisan would not be able to define all the possible sequences encompassed by the term substantially homologous.

Claim 12-16 are unclear because they recite a vector of any one of claims 1-7, however each of these claims are drawn to polypeptide sequences. The specification fails to teach vectors which are conventionally known in the art which comprise polypeptide sequences and methods of using said vector. Further, in claims 13-16 reference to a vector of claim 1-7 is recited, however no vector is described in these claims.

Claim 13 is unclear in the recitation of the TO gene, AVP gene and hGH gene because the metes and bounds encompassed by a 'gene' are not clearly defined. The specification discuses genomic sequences containing promoters, introns and exon as well as gene constructs containing polynucleotides sequences encoding the TO, AVP and hGH. It is unclear from the general use of the word gene what is encompassed by the claim.

Claim 28 is vague and unclear because it is drawn to diagnostic reagent for the intended use of detecting changes to the 5'OT EST which may predispose and individual to obesity, however the specification fails to provide a clear guidance to what this reagent(s) may be.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-12, 15, 16 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank sequence entries: AA955566, AA421393, AA505752, AA421310, AA2422211, AA245389, AA104183, AA850004, H31115, or H31114.

Claims 8-16 are drawn to nucleic acid sequences encoding a 5'OT-EST polypeptide or mutant 5'OT-EST. As noted on page 47, Example 3 and summarized in Figure 6 of the instant specification, the ESTs AA955566, AA421393, AA505752, AA421310, AA2422211, AA245389, AA104183, AA850004, H31115, and H31114, each encode a polypeptide which shares homology to the instantly claimed 5'OT EST. Thus, these sequences anticipate the claims. Claim 28 encompasses a reagent for the detection of alterations of the 5'OT EST gene which may predispose an individual to obesity. Please note that intended use limitations bear little weight on

the determination of patentability. In this case, for claims 28 the limitation for the detection of alterations of the 5'OT EST gene which may predispose an individual to obesity does not carry patentable weight in the determination of anticipation for the claimed products. This is because a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In the instant case, any polynucleotide which shares homology to the 5'OT EST gene could be used for this intended purpose because it could potentially be used to detect alterations of the gene.

Accordingly, the GenBank entries anticipate the claimed invention.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Each reference discloses the genomic sequences and orientation of the TO and AVP gene.

Schmitz *et al*. DNA and Cell Biology 10:81-91.

Mohr *et al*. Biochimie 70:649-654.

Conclusion

No claim is allowed. Claim 13 is free of the art of the art of record because of the failure of the art to appreciate the presence of the 5'OT EST gene 13 kb upstream of the TO gene, or provide motivation to link this gene or gene product, described only by EST sequences, with the TO or the AVP genes. The TO and AVP genomic sequences have been described, however these cloned sequences did not contain the 5' polynucleotide sequence which comprised the 5'OT EST gene described in the instant specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach, whose telephone number is (703) 305-3732. The examiner can normally be reached on Monday through Friday from 8:00 to 4:30 (Eastern time).

If attempts to reach the examine by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached on (703) 305-6608.

An inquiry of a general nature or relating to the status of the application should be directed to Kay Pickney whose telephone number is (703) 305-3553.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Joseph T. Woitach

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800